

Clinical Study

Incidental durotomy in degenerative lumbar spine surgery – a register study of 64,431 operations

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Abstract

BACKGROUND: Incidental durotomy (ID) is one of the most common intraoperative complications seen in spine surgery. Conflicting evidence has been presented regarding whether or not outcomes are affected by the presence of an ID.

PURPOSE: To evaluate whether outcomes following degenerative spine surgery are affected by ID and the incidence of ID with different diagnoses and different surgical procedures.

MATERIALS: By using SweSpine, the national Swedish Spine Surgery Register, preoperative, surgical and postoperative 1-year follow-up data were obtained for 64,431 surgeries. All patients were surgically treated due to lumbar spinal stenosis (LSS) without or with concomitant degenerative spondylolisthesis (DS) or lumbar disc herniation (LDH) between 2000 and 2015. Gender, age, smoking habits, walking distance, consumption of analgesics, back and leg pain (Visual Analogue Scale [VAS]), quality of life (EuroQol [EQ5D] and Short Form 36 [SF-36]), and disability (Oswestry Disability Index [ODI]) were recorded.

RESULTS: Overall, incidence of ID during the study period was 5.0%. For the LDH, LSS, and DS subgroups, it was 2.8%, 6.5%, and 6.5%, respectively. Laminectomy was associated with a higher incidence of ID than discectomy ($p < .001$). ID was more common in all three subgroups if the patient had previously been subjected to spine surgery and with increasing age of the patients ($p < .001$). LDH patients with an ID reported a higher degree of residual leg pain, inferior mental quality of life (SF-36 MCS), and higher disability (ODI) than LDH patients without ID (all $p < .001$) 1-year after surgery. LSS patients with an ID reported inferior SF-36 MCS ($p < .001$) and DS patients with an ID had inferior SF-36 MCS and higher ODI compared to patients with the same diagnosis but without an ID ($p < .001$). However, these numerical differences are well below references for MCID, for all three subgroups. ID was associated with a higher frequency of patients being dissatisfied with the surgical outcome at 1-year follow-up. In patients who did not improve in back and leg pain following surgery (delta-value), ID was less common than in patients reporting improved back and leg pain from before as compared to following surgery.

CONCLUSIONS: The overall occurrence of ID in the present study was 5%, with higher figures in LSS and DS and lower figures in LDH. Higher age of the patient and previous surgery were associated with higher frequencies of ID. The outcome at 1 year following surgery was not affected to a clinically relevant extent when an ID was obtained. However, ID was associated with a higher degree of patient dissatisfaction and a longer hospital length of stay. © 2018 Elsevier Inc. All rights reserved.

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Introduction

Incidental durotomy (ID) is defined as a perioperative nonintended tear of the dura mater causing leakage of cerebrospinal fluid. ID is one of the most common surgical complications in degenerative surgery of the lumbar spine [1–10]. The incidence varies depending on study population and diagnosis [11–14] but occurs more often in spinal stenosis surgery (incidence of 4%–9%) than in LDH surgery (incidence 2.4%) [12,14,15]. The effect of an ID on the clinical outcome is debated [7,9,11,12,14,16,17]. Some studies infer that an ID leads to an inferior early postoperative outcome [7], whereas others suggest that it does not affect the surgical outcome [9,10]. The influence of an ID on the long-term outcome is also debated [12,14,16], with reports stating that ID could have different implications in LDH and spinal stenosis surgery [7,11,12,14].

To clarify these controversies, we conducted a study by using prospectively collected data from the National Swedish Spine Register (SweSpine). Our aim was to evaluate in lumbar disc herniation and in spinal stenosis (with and without concomitant spondylolisthesis) surgery the incidence of ID with different diagnoses and different surgical procedures and the effect of ID on the clinical outcome.

Materials and methods

We studied patients included in the nationwide patient-based register SweSpine who were operated during the period from 2000 to 2015 for LDH and LSS with and without concomitant degenerative spondylolisthesis (DS). SweSpine collects data prospectively from patients treated surgically due to degenerative lumbar spine disorders. The coverage in SweSpine is currently (2017) 98% (www.4s.nu). The SweSpine is a property of The National Board for Health and Welfare and has previously been thoroughly described and validated [18–20]. Participation in the register is voluntary for both patients and clinics; participants can withdraw at any time. All patients scheduled for degenerative lumbar spine surgery are invited to participate and when a patient accepts participation, they also accept that data are used and published in forthcoming studies [20]. The present study was approved by the regional ethical review board (Dnr 2017/158).

Preoperatively, the patients report demographics (age, gender, smoking habits, and consumption of analgesics) and patient-reported outcome measurements (PROMs). The PROMs used in SweSpine are Visual Analogue Scale (VAS) for back and leg pain, Short Form 36 (SF-36), EuroQol (EQ5D), and Oswestry Disability Index (ODI). At 1, 2, 5, and 10 years postoperatively, the same metrics are registered. Surgical data related to diagnosis, operated level/s, side, type of surgery, type of implant, and complications are registered by the surgeon. The outcome data of this study refer to 1-year follow-up.

During the evaluated period, a total of 64,431 operations were registered in SweSpine. A total of 26,823 patients had

undergone surgery due to LDH (692 patients with and 26,131 without an ID), 28,248 patients due to LSS without concomitant DS (1,738 patients with and 26,510 without an ID), and 9,360 patients due to LSS with concomitant DS (608 with and 8,752 without an ID).

We used IBM SPSS statistics version 23 for the statistical calculations. Descriptive data are presented as numbers, means±standard deviations (SDs) or proportions (%). Pain by VAS, quality of life by SF-36 and EuroQol, and disability by ODI are presented as means with 95% confidence intervals (95% CI) within parentheses. Group comparisons were done using the chi-square test and Student *t* test between means or ANOVA. A *p* value <.001 was regarded as a statistically significant difference.

Results

Proportion of patients with incidental durotomy

The overall proportion of surgeries with an ID during the 16-year study period was 5.0% (2.8% in LDH surgery, 6.5% LSS surgery, and 6.5% DS surgery) (Table 1). The proportions of ID in patients with and without previous spine surgery are shown in Table 1. ID was more common in all three diagnostic groups if the patient had previously been subjected to spine surgery (*p*<.001). The annual proportion of ID for each diagnosis is reported in the Figure. No statistical trends in the proportion of ID was found over time (*p*>.05 within all three diagnosis groups).

Incidental durotomy depending on type of surgery

In LDH surgery, there was no difference in the incidence of ID in patients treated with open or microscopic discectomy (Table 2). Similar findings were observed in LSS patients operated with laminectomy or laminectomy with concomitant fusion (Table 2) and in patients with DS operated with laminectomy or laminectomy with concomitant fusion (Table 2). However, laminectomy was associated with a higher incidence of ID than discectomy (*p*<.001).

Preoperative data

LDH patients with ID during surgery were significantly older, had to a larger extent previously been subjected to spine surgery, and pre-operatively reported higher levels of back pain than LDH patients who did not sustain an ID (all *p*<.001) (Table 3). In LSS, patients with ID were significantly older, more often males, and had more frequently been previously subjected to spine surgery than patients with the same diagnosis but without ID (all *p*<.001) (Table 4). In DS, the patients who sustained an ID during surgery were significantly older, more often females, and had more frequently previously been subjected to spine surgery (all *p*<.001) (Table 5).

Table 1

Proportion of patients that sustained an ID during lumbar spine (LS) surgery for all procedures, for patients with and without previous lumbar spine surgery

	All procedures	No previous LS surgery	Previous LS surgery	p Value (comparing no previous/previous LS surgery)
All types of surgery	5.0%	4.6%	7.0%	<.001
LDH surgery	2.8%	2.4%	4.3%	<.001
LSS surgery	6.5%	6.0%	8.0%	<.001
DS surgery	6.5%	5.9%	8.7%	<.001
p Value (comparing the three diagnosis)	<.001	<.001	<.001	

Improvement following surgery

The improvement in the LDH and LSS patients reported at the 1-year follow-up was not affected by sustaining an ID (Tables 3 and 4). In DS, the improvement was inferior in patients with an ID in both mental quality of life (SF-36 MCS) and self-perceived health related quality of life (EQVAS) ($p < .001$) (Table 5).

Postoperative 1-year outcome

LDH patients with an ID, reported 1 year after surgery a higher degree of residual leg pain, inferior mental quality of life (SF-36 MCS), and higher disability (ODI) than LDH patients without ID (all $p < .001$) (Table 3). LSS patients with an ID reported at the 1-year follow-up inferior SF-36 MCS ($p < .001$) (Table 4). DS patients with an ID had at the 1-year follow-up inferior SF-36 MCS and higher ODI compared to patients with the same diagnosis but without an ID ($p < .001$) (Table 5).

Unsatisfactory outcome

Eight percent of LDH patients without ID were dissatisfied with the outcome compared to 12% with ID ($p < .001$).

The corresponding proportions in LSS patients were 13% and 17% ($p < .001$), respectively, and in DS patients 11% and 12% ($p = .26$), respectively.

Among LDH patients who reported no improvement or deterioration in back and/or leg pain from before to 1 year after surgery, 98% had no ID (97% among all LDH surgeries). The corresponding proportions in LSS patients without improvement or with worsening was 93% (93% among all LSS surgeries) and in DS patients 94% (97% among all DS surgeries). In all three patient groups, ID was associated with a 1.5-day longer LOS (length of stay) (all $p < .001$, respectively).

Discussion

ID is the one of the most common spine specific complications in degenerative lumbar spine surgery, reported with different frequencies depending on diagnosis and type of surgery performed [7,9,12]. In our study, as in previous studies, repeated spinal surgery was associated with a higher incidence of ID than primary surgery [9,10]. Furthermore, patients with LDH surgery had generally lower incidence of ID compared with patients with LSS surgery (both with and without DS). We found no time trends in the

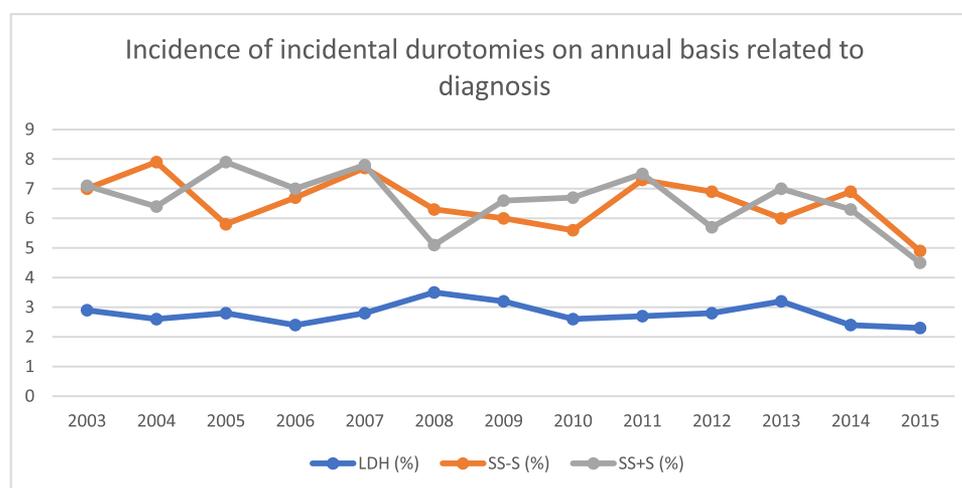


Figure. Annual proportion of ID in relation to diagnosis. Due to a few reported operations 2000–2002 the analysis includes 2003 to 2015. No significant trends were found when testing for changes over time ($p > .05$ for all three diagnoses). LDH, lumbar disc herniation; SS–S, spinal stenosis; SS+S, spinal stenosis with concomitant spondylolisthesis.

Table 2
Proportion of patients that sustained an ID within the same diagnosis but subjected to different type of operations

	Discectomy with microscopy	Discectomy without microscopy	Decompression	Decompression +fusion	p Value (between different type of operations)
LDH surgery	2.9%	2.4%	na	na	.007
LSS surgery	na	na	6.5%	6.7%	.06
DS surgery	na	na	7.6%	6.5%	.06
p Value (between different diagnosis within the same type of operation)	na	na	.01	.66	

na, not applicable.

incidence of ID during the evaluated 16-year period. Within all three diagnose groups, high age and previous spine surgery were associated with an increased risk of sustaining an ID (Tables 1–3), in accordance with previous publications [13,21,22]. However, sustaining an ID did not influence the outcome of surgery in any clinical significant way. Nonetheless, sustaining an ID seems to be associated with a lower degree of patient satisfaction with the surgical outcome, even though the outcome is not inferior and with an increased LOS.

The overall occurrence rate of ID in the present study was 5% but varied considerably depending on diagnosis and type of surgery performed. ID was significantly more common in LSS surgery than in LDH surgery. When decompressive surgery is performed, an occurrence rate of 6%–9% seems likely to be representative and comparable to what has been reported by others [23]. Adding fusion to the decompressive surgery does not increase the risk of ID.

Theoretically, the increased risk of sustaining an ID might be explained by the generally more pronounced degenerative changes in spinal stenosis patients as compared to LDH patients. In LSS, surgery is often performed at more than one level, consequently increasing the risk for

sustaining an ID. In LSS, the degeneration of the facet joints is more pronounced and sometimes there is active inflammation of the facet joints, which may lead to adherence of the joint capsule to the dura mater increasing the risk for ID. When instrumented fusion is added to laminectomy, a broader exposure of the surgical field is in general needed, which might contribute to better visualization and hence a lower incidence of ID. Also, patients operated for LSS are older and may therefore have a more fragile dura mater with a greater tendency to tear.

Patient-related risk factors for sustaining ID in the present study are previous surgery and high age. These results are in coherence with previous reports [9,10]. These factors are impossible for the surgeon to address but should raise the surgeons' awareness and may aid the surgeon in the preoperative discussion with the patient about the risk involved with surgery. The surgeons' experience questionably affects the risk for sustaining an ID but in the SweSpine the surgeons' experience with a certain procedure is not registered.

Whether the surgical outcome is affected when an ID is sustained has attracted a significant attention. In our study, the only preoperative difference in all three diagnoses was

Table 3
Baseline data related to age, gender distribution, and smoking habits, pre- and postoperative PROMs (VAS for back and leg pain, SF-36 Physical Component Summary and Mental Component Summary, EQ-index and EQVAS as well as Oswestry Disability Index) for patients surgically treated for lumbar disc herniation (LDH)

	With durotomy			Without durotomy			Comparison (p value)		
	Preop	Postop	Improvement	Preop	Postop	Improvement	Preop	Postop	Improvement
Age	49±15			45±14			<.001		
Gender (M/F)	56/44			56/44			.929		
Smoking (%)	20			20			.871		
Previous surgery (%)	21			13			<.001		
VAS	Preop	Postop	Improvement	Preop	Postop	Improvement	Preop	Postop	Improvement
Back pain	52 (50, 55)	27 (25, 30)	25 (22, 29)	48 (47, 48)	26 (25, 26)	22 (21, 23)	<.001	.143	.046
Leg pain	69 (67, 71)	27 (25, 31)	42 (38, 45)	67 (66, 67)	22 (22, 23)	45 (44, 45)	.016	<.001	.103
SF-36									
PCS	37 (36, 38)	46 (44, 47)	8 (7, 10)	37 (37, 37)	46 (46, 46)	10 (9, 10)	.286	.212	.062
MCS	29 (28, 30)	41 (40, 42)	12 (11, 14)	31 (30, 31)	43 (43, 44)	13 (13, 13)	.003	<.001	.434
EQ5D-index	0.26 (0.24, 0.29)	0.66 (0.64, 0.70)	0.42 (0.38, 0.46)	0.25 (0.25, 0.26)	0.70 (0.70, 0.71)	0.45 (0.44, 0.46)	.551	.008	.234
EQVAS	44 (42, 46)	67 (65, 69)	24 (21, 27)	45 (45, 45)	71 (70, 71)	26 (26, 27)	.455	.002	.193
ODI	51 (49, 52)	23 (21, 25)	28 (26, 30)	48 (48, 49)	20 (20, 20)	29 (28, 29)	.003	<.001	.464

Data are presented as mean±standard deviations (SD), mean with 95% confidence intervals (95% CI) within parentheses or as proportions (%). Significant differences are highlighted in bold.

Table 4

Baseline data related to age, gender distribution and smoking habits, pre- and postoperative PROMs (VAS for back and leg pain, SF-36 Physical Component Summary and Mental Component Summary, EQ-index and EQVAS as well as Oswestry Disability Index) for patients surgically treated for spinal stenosis without concomitant spondylolisthesis (LSS)

	With durotomy			Without durotomy			Comparison (p value)		
	Preop	Postop	Improvement	Preop	Postop	Improvement	Preop	Postop	Improvement
Age	70±11			68±11			<.001		
Gender (M/F)	51/49			46/54			<.001		
Smoking (%)	13			11			.025		
Previous surgery (%)	25			19			<.001		
VAS	Preop	Postop	Improvement	Preop	Postop	Improvement	Preop	Postop	Improvement
Back pain	56 (55, 58)	36 (34, 38)	21 (19, 23)	56 (56, 56)	35 (34, 37)	20 (18, 22)	.828	.360	.798
Leg pain	62 (61, 64)	36 (34, 38)	26 (24, 29)	63 (63, 63)	35 (34, 35)	29 (28, 29)	.182	.225	.014
SF-36									
PCS	41 (40, 42)	45 (45, 46)	4 (3, 5)	41 (41, 41)	46 (45, 46)	5 (4, 5)	.575	.585	.342
MCS	28 (28, 29)	35 (34, 36)	7 (6, 8)	28 (28, 29)	36 (36, 36)	8 (8, 8)	.116	<.001	.004
EQ5D	0.37	0.61	0.23	0.36	0.62	0.26	.460	.075	.009
	(0.35, 0.39)	(0.58, 0.62)	(0.20, 0.25)	(0.35, 0.36)	(0.62, 0.63)	(0.25, 0.26)			
EQVAS	48 (47, 50)	62 (60, 63)	14 (12, 16)	48 (48, 49)	63 (63, 64)	15 (15, 16)	.673	.067	.112
ODI	44 (43, 45)	29 (28, 31)	15 (13, 16)	43 (43, 44)	28 (27, 28)	16 (16, 16)	.471	.003	.082

Data are presented as mean±standard deviations (SD), mean with 95% confidence intervals (95% CI) within parentheses or as proportions (%). Significant differences are highlighted in bold.

in LDH surgery patients were patients who sustained an ID reported a higher degree of back pain. These findings may perhaps be related to more pronounced degenerative changes in these patients making them more susceptible for ID. Improvements in LDH patients and LSS patients were not affected by sustaining an ID. Patients with DS who sustained ID reported inferior improvement in SF-36 MCS and EQVAS. At follow-up, patients with ID reported inferior SF-36 MCS in all three diagnose groups. Patients surgically treated for LDH and DS who sustained an ID had a higher ODI and LDH patients who sustained an ID had a higher degree of residual leg pain. When evaluating these findings in the present study, the numerical differences between

patients with and without an ID are below the clinically important difference (MCID) for the different PROMs [24–26]. The differences should in our opinion be regarded as being of no or minor clinical importance, in spite of statistically significant difference. This notion is supported by previous reports in the literature [9,10] A recent prospective Swiss study including 167 patients reported an ID rate of 9% with no effect on the clinical long-term outcome [12] and that an ID in LSS surgery does not influence the level of postoperative back and leg pain or disability (ODI). Another report on LSS surgery, including 800 patients [16], showed that an ID is associated with inferior clinical outcome [27]. In LDH surgery, similar ID incidence has been

Table 5

Baseline data related to age, gender distribution and smoking habits, pre- and postoperative PROMs (VAS for back and leg pain, SF-36 Physical Component Summary and Mental Component Summary, EQ-index and EQVAS as well as Oswestry Disability Index) for patients surgically treated for Spinal Stenosis with concomitant spondylolisthesis (DS)

	With durotomy			Without durotomy			Comparison (p value)		
	Preop	Postop	Improvement	Preop	Postop	Improvement	Preop	Postop	Improvement
Age	71±9			68±10			<.001		
Gender (M/F)	25/75			29/71			<.001		
Smoking (%)	11			11			.304		
Previous surgery (%)	23			16			<.001		
VAS	Preop	Postop	Improvement	Preop	Postop	Improvement	Preop	Postop	Improvement
Back pain	58 (56, 61)	34 (31, 36)	25 (21, 28)	60 (59, 60)	31 (30, 32)	28 (27, 29)	.347	.066	.129
Leg pain	66 (63, 68)	34 (31, 37)	31 (27, 35)	64 (64, 65)	31 (30, 32)	34 (33, 35)	.223	.038	.202
SF-36									
PCS	41 (40, 42)	46 (45, 47)	6 (4, 8)	41 (40, 41)	47 (46, 47)	6 (5, 6)	.894	.155	.499
MCS	28 (27, 29)	34 (33, 36)	7 (5, 8)	28 (28, 28)	37 (37, 37)	9 (9, 9)	.260	<.001	<.001
EQ5D	0.35	0.62	0.26	0.34	0.64	0.30	.592	.058	.055
	(0.32, 0.38)	(0.59, 0.65)	(0.22, 0.30)	(0.33, 0.35)	(0.64, 0.65)	(0.29, 0.31)			
EQVAS	48 (46, 50)	62 (59, 64)	14 (11, 18)	46 (46, 47)	65 (65, 66)	19 (18, 20)	.097	.002	<.001
ODI	46 (44, 47)	29 (27, 31)	17 (15, 19)	44 (44, 45)	26 (25, 26)	18 (18, 19)	.029	<.001	.216

Data are presented as mean±standard deviations (SD), mean with 95% confidence intervals (95% CI) within parentheses or as proportions (%). Significant differences are highlighted in bold.

reported without affecting the outcome of surgery [9]. Even if the outcome is not inferior in patients with ID, the risk of being dissatisfied with the surgical outcome at 1 year post-operatively is increased in patients with ID.

As in previous studies, higher age [13] and previous spine surgery were associated with a higher incidence of ID [21,22]. The present study adds knowledge and reinforces the opinion that adding fusion to laminectomy in LSS surgery is not associated with an increased risk for ID. These findings agree with other reports concluding that fusion in LSS surgery is not associated with an increased risk for ID [22]. Results from other studies have however opposed this view [14]. Furthermore, DS does not appear to increase the risk of sustaining an ID, which is a finding also supported by others [14].

The present study is the largest on the subject of ID in the literature. The use of prospectively collected data and validated PROMs add strength to our study. Furthermore, inclusion of three large cohorts with different diagnoses and different surgical procedures and a long follow-up period allows for reliable time trend calculations. Although this is a nationwide survey, the figures represent everyday health care and not results achievable only in a controlled study. Weaknesses include the risk for selection bias, that specific groups of patients may not participate and that there may be selection of patients who are lost to the 1-year follow-up. However, a recent validation of SweSpine [28] revealed that the patients lost to follow-up did not differ from the ones included at the follow-up and hence seem to represent a random selection. Another concern is that the diagnosis, the surgical procedure and the reporting of ID are entirely based on reports from the operating surgeon, which may infer underreporting of the ID.

We conclude that an ID is more frequent in LSS surgery than in LDH surgery and that no changes have occurred in the incidence of ID over time. Previous spine surgery and higher age seem to be firm risk factors for ID. However, ID does not influence the surgical outcome in a clinically relevant way but is associated with a higher frequency of dissatisfied patients and an increased LOS.

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